

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER
3178 USOP

U.S. APPLICATION NO. (If known, see 37 CFR 1.52)
10/561483

INTERNATIONAL APPLICATION NO.
PCT/JP2004/009355

INTERNATIONAL FILING DATE
June 25, 2004

PRIORITY DATE CLAIMED
June 26, 2003

TITLE OF INVENTION

CANNABINOID RECEPTOR MODULATOR

APPLICANT(S) FOR DO/EO/US

Shigenori OHKAWA; Tetsuya TSUKAMOTO; Yoshihiro KIYOTA; Mika GOTO; Shouzou YAMAMOTO; Masato SHIMOJOU; Masaki SETO

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

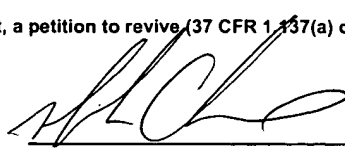
Items 11 to 20 below concern document(s) or information included:

- Cited References**

 11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
 12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
 13. ☒ A preliminary amendment.
 14. ☐ An Application Data Sheet under 37 CFR 1.76.
 15. ☐ A substitute specification.
 16. ☐ A power of attorney and/or change of address letter.
 17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
 18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
 19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
 20. ☒ Other items or information: Return Postcard; Certificate of Express Mailing; Cover Page International Application; Forms PCT/IB/301,304,306,308; ISR

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/561483		PCT/JP2004/009355		3178 USOP	
21. The following fees are submitted:					
<input checked="" type="checkbox"/> a) Basic national fee.....				\$300.00	\$
<input checked="" type="checkbox"/> b) Examination fee.....				\$200.00	\$
<input checked="" type="checkbox"/> c) Search fee.....				\$500.00	\$
TOTAL OF ABOVE CALCULATIONS =				\$1000.00	\$ 1,000.00
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)		RATE	
640 - 100 =	540 /50 =	11		x \$250.00	\$ 2,750.00
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).					\$
CLAIMS	NUMBER FILED		NUMBER EXTRA	RATE	\$
Total claims	39 - 20 =		19	x \$50.00	\$ 950.00
Independent claims	10 - 3 =		7	x \$200.00	\$ 1,400.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$360.00	\$
TOTAL OF ABOVE CALCULATIONS =					\$ 6,100.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.					\$
SUBTOTAL =					\$ 6,100.00
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).					\$
TOTAL NATIONAL FEE =					\$ 6,100.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property					\$ 40.00
TOTAL FEES ENCLOSED =					\$ 6,140.00
					Amount to be refunded:
					\$
					Amount to be charged:
					\$ 6,140.00
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>500799</u> in the amount of \$ <u>6,140.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>500799</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.437(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Mark Chao, Ph.D., JD					
Takeda Pharmaceuticals North America, Inc					
475 Half Day Road					
Lincolnshire, IL 60069 USA					
(847)383-3372 fax (847)383-3409					
 SIGNATURE Mark Chao, Ph.D., JD NAME 37,293 REGISTRATION NUMBER For Customer No. 23,115					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	Based on PCT/JP2004/009355	Art Unit:	tba
Filed:	Intl. Filing 25 JUNE 2004	Examiner:	tba
1 st Inventor:	Shigenori OHKAWA	Allowed:	
For:	Cannabinoid Receptor Modulator	Batch:	
Atty. Dkt. No.	3178 USOP	Paper No.:	

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL. No. EV 684083811 US

DATE IN: December 20, 2005

Itemized Papers/Items:

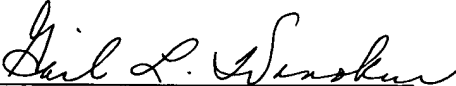
1. This Return Postcard Certificate of Express Mailing (2 pages)
2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
3. Specification - total pages- 640, including Claims 1-39 (pages 626-639, and Abstract (1 page),
4. Declaration and Power of Attorney (6 pages)
5. Copies of Forms PCT/IB/301, 304, 306, 308 (7 pages)
6. Copy of Cover Page International Application (WO 2005/000829) (1 page)
7. Copy of International Search Report (4 pages)
8. Preliminary Amendment (5 pages)
9. Mark up of specification tables (5 pages); and substitute pages (5 pages)
10. Executed Assignment (2 pages) and Recordation Cover Sheet (1 page X 2)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP PCT
P.O. BOX 1450
Commissioner for Patents
Alexandria, VA 22313-1450

on this date, 12/20/05

Dated: 12/20/05


Gail L. Winokur

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
475 Half Day Road
Lincolnshire, IL 60069 USA